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10/518,866

01/30/2006

Chad Munro

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EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

09/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/518,866 | Applicant(s) MUNRO ET AL. | |
| | Examiner Anu Ramana | Art Unit 3775 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/30/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to because of heavy shading (see Fig. 8). Further, the heavy shading has obscured the lead lines for the reference numerals making it difficult to understand details of Applicant's invention. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Specification

The disclosure is objected to because it appears to be a direct translation of a foreign language document, making it impossible to understand the various elements of Applicant's invention and interaction or operation thereof. For e.g. see para [0016].

Appropriate correction is required.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, the recitations "front threaded flank" and "rear threaded flank" render the claim vague and indefinite since the structure being claimed is unclear. It appears that Applicant is claiming the thread to have a front flank or face and a rear flank or face.

Further, in claims 1 and 12, the recitation "flank piece" renders the claim vague and indefinite because it is unclear what structure is being claimed. Does Applicant mean a portion of a turn of the external thread at the tip of the screw? Additionally, the recitation "which is angled with respect to threaded flanks, so that a tangential cutting edge is formed thereby at the front end of the thread" renders the claim vague and indefinite since the structure being recited is unclear. The tangential cutting edge of Applicant's invention is formed on a turn of an external thread at the tip of the screw.

In claim 2, the recitation "flank piece encloses an angle" renders the claim vague and indefinite since it is unclear what structural relationship is being claimed.

In claim 5, the recitation "preferably as a double thread" renders the claim vague and indefinite since it is unclear whether the external thread is a double thread or not.

In claims 3, 6 and 8-10, the recitations "more preferably between" or "preferably of" or "preferably between" render the claims vague and indefinite because use of a narrower range within a broader range in the same claim renders the claim indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. One could not tell from such a claim if the narrower range or limitation is a restriction or limitation on the broader range or limitation.

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In claim 7, the recitation "thread pitch $X = nx$ " renders the claim vague and indefinite since the relationship being claimed is unclear.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Ross et al. (US 5470334).

Ross et al. disclose an assembly including: a bone screw 10 having an external thread with a front face directed towards the front threaded end and a rear face directed toward the rear threaded end; and a cannulated driver or "tubular bone blade" coaxial with the bone screw when attached to the bone screw (Figs. 1, 3 and 5, col. 4, lines 27-67, cols. 5 and 6 and col. 7, lines 1-35).

Ross et al. also disclose the screw to have a flank piece or portion of a turn to have an angled surface that forms a tangential cutting edge. See marked up Fig. 1 below.

It would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the cutting edge of the Gambale screw at an angle of about 40 degrees to about 110 degrees with the longitudinal axis because Applicant has not disclosed that providing a specific angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Gambale screw and applicant's invention, to perform equally well with either the angle taught by Gambale et al. or the claimed "about 40 degrees and about 110 degrees" or "about 85 degrees and about 95 degrees," because both angles would perform the same function of fixing the screw in bone.

Claim 5-6, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. (US 6440136) in view of Schlapfer et al. (US 6585740).

Gambale et al. discloses all elements of the claimed invention except for: (1) the pitch of the threads; (2) a variable flank or thread angle; and (3) a flank angle in a range of about 5 degrees and 160 degrees with respect to the longitudinal axis of the screw.

It is well known in the art to provide a bone screw with a pitch of about 1.5 mm to about 4 mm, a single thread with a thread angle between 5 degrees and 18 degrees or a double thread with a thread angle between 10 degrees and 22 degrees, as evidenced by Schlapfer et al. (col. 3, lines 3-12 and col. 4, lines 12-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Gambale et al. screw with a pitch of about 1.5 mm to 4 mm, a variable flank or thread angle or a flank angle between 5 degrees and 18 degrees, as taught by Schlapfer et al. for improved resistance to tearing, cutting and bending and good hold in bone. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a flank angle in a range of about 5 degrees to about 160 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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Claim 5-6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. (US 6440136) in view of Pritchard (EP 0476831A1) and Ferrante (US 5565573).

Gambale et al. discloses all elements of the claimed invention except for: (1) the pitch of the threads; (2) a height of the thread profile between 0.5 mm and 5 mm; and (3) a flank angle in a range of about 5 degrees and 160 degrees.

Gambale also doesn't disclose a range of the external diameter of the screw.

It is well known in the art to provide a self-tapping screw with a pitch of about 2.7 mm to about 6 mm (for a nominal screw diameter of 6-10 mm); a thread diameter of 1.4 mm to 10 mm; a thread height that is two times thread pitch (i.e., 5 mm to 12 mm); and a thread angle between 100 to 105 degrees with respect to the longitudinal axis, as evidenced by Pritchard (cols 3, 4 and 5). Pritchard also discloses a single-start or a two-start helical thread. It is noted that the size and diameter of a screw used for surgical purposes is a function of the patient bone's conditions. Pritchard correlates the pitch and height of an external thread to the screw diameter.

It is well known to use screws with external diameters in a range of 3.5 mm to 6.0 mm for orthopedic applications. Additionally, the diameter of the screw depends on the function of the screw (see col. 7, lines 59-66 of Ferrante).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Gambale et al. screw with an overall diameter in a range of 3.5 mm to 6 mm resulting in a pitch of about 1.5 mm to 3 mm, a variable flank or thread angle or a flank angle between 100 and 105 degrees, as taught by Pritchard for improved load bearing characteristics of the screw. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided: (1) an external diameter of about 10 mm to about 14 mm; (2) a thread profile height between 0.5 mm to 5 mm; or (3) a flank angle in a range of about 5 degrees to about 160 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
September 6, 2010

/Anu Ramana/
Primary Examiner, Art Unit 3775